DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

Rizhao Huge Dental Industry Co., LTD
C/O Ms. Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room 302, No. 21 Building
Kaiyu Garden, Xishan South Road
Wenzhou, 325000
Zhenjiang Province, CHINA

Re: K141162
Trade/Device Name: All-Ceramic Zirconia Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 15, 2014
Received: June 04, 2014

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141162

Device Name
All-Ceramic Zirconia Block

Indications for Use *(Describe)*
The product is indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns,facings, and veneers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

· Intended Use:

The product is indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns,facings, and veneers.

5.3 Comparison of Required Technology Characteristics

Item		Subject Device	Predicate Device
Indication for Use		Indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns,facings, and veneers.	Indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns,facings, and veneers.
Material of Construction		Zirconia Powder	Zirconia Powder
Physical & Mechanical Properties	Crystal Morphology	HS&HTIII: Tetragonal	Tetragonal
	Color	HS&HTIII: White	White
	Density (pre sintering)	HS:3.10g/cm^3	3.10g/cm^3
		HTIII:3.30g/cm^3	
	Density (post sintering)	HS&HTIII: 6.0-6.1g/cm^3	6.05g/cm^3
	Fracture Toughness (pre sintering)	HS: 53.48Mpa	55Mpa
		HTIII: 54.9Mpa	
	Fracture Toughness (post sintering)	HS&HTIII: 1250Mpa	1200Mpa
	Elastic modulus (post sintering)	HS&HTIII: 210Gpa	210Gpa
	Sintering	HS:1500℃	1480℃

	temperature	HTIII: 1450℃	
	Shrinkage (pre sintering)	HS: 0.3%	20.00%
		HTIII: 1.02%	
	Shrinkage (post sintering)	HS: 20%	22.00%
		HTIII: 18.4%	
	Porosity	HS & HTIII: 0%	0%
Shapes & Sizes		2 product families, 2 shapes and 8 sizes	7 different product families of shapes and a multitude of different sizes
Effectiveness		Tested According to ISO 6872	Tested According to ISO 6872
Safety		Tested According to ISO 10993-3, -5, -10, -11.	Evaluated according to ISO 10993-1.

Brief Summary:

First, the subject device - All-Ceramic Zirconia Block incorporates the same intended use with the predicate device. Secondly, the subject device is composed of the same material - zirconia powder with the predicate device. Thirdly, the two devices are similar in physical&Mechanical properties. Also, both their safety and effectiveness have been verified by appropriate FDA recognized standards.

Though they are not identical in shapes and sizes, such minor difference will not influence the core usage of the device, thus will not affecting the devices' substantial equivalence.

5.4 Discussion of Tests Performed

· Clinical Tests:

Clinical testing was not performed for Aidite Zirconia Dental Ceramics as part of the Pre-market Notification requirements for this submission, as dental ceramics that fall under FDA product code EIH have a long history of safe and effective use in the US.

· Non-Clinical Tests

The subject device was tested to evaluate its safety and effectiveness according to the following standards:

- Biocompatibility Test according to AAMI / ANSI / ISO 10993-3:2003/(R)2009, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. (Biocompatibility), AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility), AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility) and AAMI / ANSI / ISO 10993-11:2006/(R)2010, Biological Evaluation Of Medical Devices -- Part 11: Tests For Systemic Toxicity. (Biocompatibility)
- Device Effectiveness according to ISO 6872 Third Edition 2008-09-01, Dentistry - Ceramic Materials. (Dental/ENT)

5.5 Conclusion:

First, the subject device - All-Ceramic Zirconia Block enjoys the same intended use and similar technological characteristics with the predicate device. Besides, the performance safety and effectiveness of the subject device has been verified in accordance with the above FDA recognized standards, thus being considered to be as safe and effective as the predicate device.

In a word, it is reasonable for us to conclude that the subject device is substantially equivalent to the predicate device according to the above analysis.

Section 5 510(k) Summary

(As required by 21 CFR 807.92(a))

5.1 Submitter Information

· Company: Rizhao Huge Dental Industry Co.,Ltd

· Address: No.68 Shanhai Road, Rizhao City, 276800, Shandong Province, China

· Phone: 086-633-2277285

· Fax: 086-633-2277298

· Contact: Steven Song, General Manager

· Date: April 15, 2014.

5.2 Device Information

· Trade/Device Name: All-Ceramic Zirconia Block

· Trademark: zirking

· Product Family: HS & HTIII

· Classification: Device Class: 2
Review Panel: Dental
Name: Powder, Porcelain
Regulation Number: 21 CFR 872.6660
Product Code: EIH

· Predicate Device: Aidite Zirconia Dental Ceramics submitted by
Qinhuangdao Aidite High-Technical Ceramics Co.
K Number: K111291

· Device Description:

The product is casted by cold isostatic cool pressuring and processed by pre-sintering with zirconia powder as the material.

There are two product families within our subject device - HS Series and HTIII Series, which are quite similar in Physical & Mechanical Properties. And the two product families all boast two shapes - the ones without steps and the ones with 2 steps, and eight sizes - 98×10mm for the ones without steps and 98×12mm, 98×14mm, 98×16mm, 98×18mm, 98×20mm, 98×22mm and 98×25mm for the ones with 2 steps.

· Intended Use:

The product is indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns,facings, and veneers.

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		HTIII: 18.4%	
	Porosity	HS & HTIII: 0%	0%
Shapes & Sizes		2 product families, 2 shapes and 8 sizes	7 different product families of shapes and a multitude of different sizes
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